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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

February 15, 2002

Patricia Sacks, M.D.
Radiology Director
Torrance Memorial Breast Diagnostic Center II
824 East Carson Street; Suite #208
Carson, CA 90745-2262

W/L Number: 29 - 02
Inspection ID: 2151860005
CFN: 20-32,194
FEI: 3003146706

Dear Dr. Sacks:

We are writing to you because on February 11, 2002, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- Level 1: Mammograms were processed in processor #1 (a [redacted] machine), which is located in the daylight room, when it was out of limits on at least five (5) days. Specifically, while the new aim values were being established after a processor chemistry change, the processor was out of limits. For some period of time, you were using two (2) "channel" data charts showing that on one chart the data was out of limits while the second chart was in limits. [Title 21 Code of Federal Regulations 900.12(e)(1)]

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation

of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction (DPC), charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. The Level 2 finding is:

- Level 2: The mammography processor equipment evaluation (by a medical physicist) for processor #1 (a [redacted] machine) was not performed. Specifically, on January 28, 2001 your facility changed processor chemistry. After establishing new aim values, you failed to contact a MQSA-qualified medical physicist to re-evaluate all processor and phantom QC. [21 Code of Federal Regulations 900.12(e)(9)]

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not

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necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (telephone number: 1-800-838-7715) or through the Internet at http://www.fda.gov

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to Scott Goff (the Compliance Officer assigned to this case) at telephone number 949-798-7644.

Sincerely,

Alonza E. Cruse
District Director

cc.

Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
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